Section 4: 510(k) Summary

4.1 General Provisions

Submitter's Name and Address	Boston Scientific, Inc. One Scimed Place Maple Grove MN 55311
Contact Person	Candice R. Burns Regulatory Affairs Specialist 763-494-2845
Classification Name	Biliary Catheter and Accessories Product Code – 78 FGE Regulation Number 21 CFR Part 876.5010
Common or Usual Name	Biliary Stent and Balloon Dilatation Catheter
Proprietary Name	Boston Scientific Corporation Express Biliary SD Premounted Stent System

4.2	**Name of Predicate Device**	Johnson and Johnson Corinthian™ IQ Transhepatic Biliary Stent and Delivery System and Ultra-soft SV Balloon Dilatation Catheter
4.3	**Device Description**	The Express Biliary SD Premounted Stent System is available in the models indicated in Table 4.3. A brief description of the device components follows.

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4.3 Device Description (continued)

Table 4.3 Device Description

Balloon Diameter mm	Balloon Length mm	Crimped Stent Length mm	Stent Diameter mm	Rated Burst Pressure atm [kPa]	Catheter Length cm
4	16, 20	15, 19	4	14 [1419]	90, 150
5	16, 20	15, 19	5	14 [1419]	90, 150
6	15, 19	14, 18	6	14 [1419]	90, 150
7	16, 20	15, 19	7	14 [1419]	90, 150

4.3.1 Stent

The Express Biliary SD stent is a balloon expandable metallic stent intended to maintain patency of biliary strictures produced by malignant neoplasms. The stent will be available in a variety of sizes to address clinician needs.

The Express Biliary SD stent is made from 316L surgical grade stainless steel. The stent geometry is a laser-cut pattern consisting of large and small sinusoidal bands connected by axial struts. Additional struts are provided to reinforce the three connector rows of the proximal stent end, resulting in additional scaffolding designed to reduce tumor in-growth at the proximal stent end.

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4.3.2 Delivery System

The delivery system for the Express Biliary SD Premounted Stent System consists of a Monorail™ catheter with a stent crimped on a balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The distal segment of the balloon catheter is dual lumen and coaxial. The outer lumen is used for inflation of the balloon. The wire lumen permits the use of guidewires (≤0.018 in / 0,46 mm) to facilitate advancement of the catheter to and through the stricture to be dilated.

4.4 Intended Use

The Express Biliary SD Premounted Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

4.5 Summary of Technological Characteristics

The Express Biliary SD Premounted Stent System will incorporate a substantially equivalent design, method of deployment, packaging, fundamental technology, manufacturing, sterilization and intended use as those featured in the predicate Johnson and Johnson Legally marketed Corinthian IQ Biliary Stent and Delivery System.

4.6 Non-clinical Test Summary

Functional testing for the stent component includes:

- Bile corrosion resistance
- Tensile and elongation
- Foreshortening
- Expanded stent length
- Recoil
- Expansion uniformity
- Compression resistance/radial hoop strength
- Over-expansion
- Deployment pressure, accuracy and diameter

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4.6 Non-clinical Test Summary (continued)

Functional testing for the delivery system includes:

- Repeat balloon inflation within a stent
- Balloon burst within the stent
- Balloon/delivery system distension and compliance labeling
- Balloon inflation and deflation time
- Catheter tensile strength
- Stent/balloon crossing profile
- Stent securement force
- Shelf life testing
- Biocompatibility Assessment

Product shelf life testing will be conducted and completed prior to the commercialization of this device. The shelf-life data must show acceptable results after 3 years of accelerated age testing in order to claim the labeled shelf life of 3 years.

Based on a comparison of intended use, design, and results of *in-vitro* testing, the Express Biliary SD Premounted Stent System is adequate for the intended use and is considered substantially equivalent to the legally marketed Johnson & Johnson Corinthian IQ Transhepatic Biliary Stent with Delivery Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2004

Ms. Candice Burns
Regulatory Affairs Specialist
Boston Scientific Corporation
One Scimed Place
MAPLE GROVE MN 55311-1566

Re: K040027
Trade/Device Name: Boston Scientific Express™ Biliary SD Premounted Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: January 7, 2004
Received: January 8, 2004

Dear Ms. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K040027

Device Name: Boston Scientific Express™ Biliary SD Premounted Stent System

FDA's Statement of the Indications For Use for device:

The Boston Scientific Express™ Biliary SD Premounted Stent System is indicated for the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040027